REMARKS AND STATEMENT OF STATUS AND SUPPORT FOR ALL CHANGES TO THE CLAIMS

Claims 1-23, as issued, are pending in the reissue application. Claims 1, 10, 14, 16, 19, 21, and 23 are amended. Claims 24-26 are new.

Reissue is sought to broaden claims 1, 10, 14, 19, 21, and 23 by removing the word "tablet," so as to clarify that the formation of the recited reagent composition(s) may be any of those forms supported by the specification. New claims 24-26 further limit the claims from which they depend by stating that the reagent composition is in the form of a tablet. Support for these amendments to claims 1, 10, 14, 16, 19, 21, and 23, and for the addition of claims 24-26, is found in the specification as a whole, and in particular at column 3, lines 62-65 ("...which may be solid, liquid, powder, emulsion, suspension, tablet or substantially any combination separately or admixtured thereof.").

Claim 1 is further amended by deleting the phrase "...for use in the detection of the test sample and sealed..." This phrase merely states an intended use of the claimed device and is not considered essential to patentability.

Claim 14 is further amended to add the terms "first" and "second" for the purpose of antecedent basis.

Claim 16 is further amended to clarify the antecedent basis of the recited reagent composition.

The claim amendments submitted herein were formatted according to the guidance provided by the *Manual of Patent Examination*, pages 1400-55 to 1400-58 (8th Edition, August 2001). If an alternative format is required, please notify the undersigned.

CONCLUSION

Please charge any outstanding fees due, or overpayments, to Deposit Account No. 50-1895, Reference No. 0656-008US6.

Acceptance of this Preliminary Amendment and Statement Of

Status And Support For All Changes To The Claims is respectfully requested.

Date: 12/4/01

Respectfully submitted,

lestie Meyer Jeon

Leslie Meyer-Leon, Esq. Attorney for Applicant

Reg. No. 37,381

IP Legal Strategies Group P.C.

901 Main Street

P.O. Box 280

Osterville, Massachusetts 02655-0280

Tel: (508) 428-4000 Fax: (508) 428-1900

Enclosures:

copy of specification of U.S. Patent

No. 6,180,395B1

copy of drawings of U.S. Patent No. 6,180,395Bl copy of Terminal Disclaimer from U.S. Patent

No. 6,180,395B1

Reissue Application Declaration By The Inventor

Consent of Assignee

Statement Under 37 C.F.R. 3.73(b) Information Disclosure Statement

copy of cited references

Version Of Claims With Markings To Show Changes Made

Claim 1 (Amended). A unit dose reagent chamber for use in a test apparatus for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in a test sample, and wherein a moveable probe is employed to obtain a test sample and to release reagents from the reagent chamber to a test unit, which unit dose chamber comprises:

- a) a cylinder having a one open end and an other opposite open end;
- b) a probe-puncturable membrane seal over the one end and the other end of the cylinder to form a sealed compartment; and
- c) a reagent composition [for use in the detection of the test sample and sealed] within the sealed compartment, which composition consists essentially of and is selected from the group consisting of:
- i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for testing;
- ii) a reaction stopping solution having a pH of $^{\circ}$ 8 to 11; and
- iii) a luciferin-luciferase or phosphatase
 substrate reagent [tablet].

Claim 10 (Amended). The combination of claim 7 wherein the sealed compartment comprises the buffered-detergent solution and

a luciferase and a luciferin reagent [in tablet form] at the bottom end of the test unit.

Claim 14 (Amended). A test apparatus for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in a test sample, by luminescence or color, which test apparatus comprises:

- a) a longitudinal test apparatus housing having a one
 end and an other end;
- b) a moveable probe within the housing to collect a test sample and arranged to puncture a membrane seal;
- c) a transparent test unit having a one end and a closed bottom end extending from the one end of the housing for use in detecting luminescence or color in the test sample, and a first reagent [tablet] composition to detect adenosine triphosphate (ATP) or alkaline phosphatase (AP), by color or luminescence, at the closed bottom end; and
- d) one or more unit dose reagent chambers longitudinally-positioned in the test unit, which reagent chamber comprises:
- i) a cylinder having a one open end and an other opposite open end;
- ii) a probe-puncturable membrane seal at and over the one end and the other end of the cylinder to form a sealed compartment; and

iii) a <u>second</u> reagent composition for use in the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the test sample and sealed within the sealed compartment, which reagent composition comprises a buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution for subsequent reaction with the <u>first</u> reagent [tablet] <u>composition</u>.

Claim 16 (Amended). The apparatus of claim 14 wherein the second reagent composition comprises a phosphoric acid and a detergent solution.

Claim 19 (Amended). The apparatus of claim 14 wherein the sealed compartment comprises a buffer-detergent solution and a luciferase and a luciferin substrate, as a reagent, is at the bottom end of the test unit.

Claim 21 (Amended). A transparent test unit for use in a test apparatus, for the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP), and which test unit comprises: a one open end; a closed bottom end; a probe-puncturable membrane over the one end; and the one end having threads for threadable attachment of the test unit to the test apparatus, and the test unit having one or more separate, longitudinally-aligned unit dose reagent chambers, which unit dose chamber comprises:

- a) a cylinder having a one open end and an other opposite open end;
- b) a probe-puncturable membrane seal over the one end and the other end of the cylinder to form a sealed compartment;
- c) a reagent composition for use in the detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the test sample and sealed within the sealed compartment, which comprises a buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into the solution; and
- d) a reagent [tablet] <u>composition</u> at the bottom end to detect the adenosine triphosphate (ATP) or alkaline phosphatase (AP) in the solution.

Claim 23 (Amended). The test unit of claim 21 wherein the test unit includes a luciferin-luciferase reagent [tablet].